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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/341,821	09/01/1999	MICHAEL J. WARING	CV0244	5635

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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1615	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/341,821	WARING ET AL.	
	Examiner	Art Unit	
	Isis A. Ghali	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 July 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5,6,8-10,14,15 and 18-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5, 6, 8-10, 14, 15 and 18-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicants' request for reconsideration filed 07/03/2007.

Claims 5, 6, 8-10, 14, 15, 18-20 are pending and included in the prosecution.

The following rejections have been discussed in details in the previous office action, and are maintained for reasons of record:

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 5, 6, 8-10, 14, 15, 18-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are confusing as they recite the barrier aerosol is "self-sealing". The specification does not provide definition of what it means to be "self-sealing" or structure necessary to meet this limitation. According to the specification, page 2, lines 18-20, "because there is positive pressure in the container, the vessel can be made to be self-sealing". This aids maintenance of wound gel sterility, see page 2, lines 20-21 of the present specification.

It is also stated in the present specification that when the product container is sealed with the "opening valve", number 14 of figure 1 of the present drawing, after filling and steam sterilization, "pressure medium can then be introduced into the second compartment without compromising the sterility of the product", page 4, lines 6-11; page 4, line 34-page 5, line 5. Experiments that mimicked clinical use (i.e., discharge of gel from the opening valve) were performed to show that that "micro-organisms do not proliferate in the gel contained in the barrier vessel", page 8, line 28-page 9, line 17. In view of the specification's reference to the opening valve with respect to maintaining wound gel sterility, the examiner interprets the claimed requirement that the vessel is "self-sealing" to be a property of the opening valve. Additionally, "self-sealing" is interpreted to have its "ordinary and customary meaning" (Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582, 39 USPQ2d 1573, 1576 (Fed. Cir. 1996)), i.e., to seal by itself ("self") without assistance. Making the vessel self-sealing protects the product contained in the aerosol vessel from contamination by sealing it up after the product has been discharged. This is consistent with the vessel's purpose to package a wound gel in multi-dose packaging which minimizes contamination once opened, page 2, lines 9-11. Neither the claims nor the specification require the self-sealing opening valve to have a particular structure. In sum, the examiner construes "self-sealing barrier aerosol vessel" to be a vessel having a first compartment for containing the wound gel and second compartment, which is isolated from it, that contains pressurized gas to facilitate discharge of the wound gel from the vessel. The first compartment comprises a valve or port, through which gel can be introduced into the vessel or discharged from it,

and which seals up by itself after a single dosage of gel is expelled from the vessel. However, claims must be read in view of the specification, of which they are a part. The specification is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term. Phillips v. AWH Corp., 415 F.3d 1303, 1315, 75 USPQ2d 1321, 1327 (Fed. Cir. 2005).

Response to Arguments

3. Applicant's arguments filed 07/03/2007 have been fully considered but they are not persuasive. Applicants argue that the expression "self sealing" is well defined and clear. It is noted that the Action explains that the expression "is interpreted to have its 'ordinary and customary meaning' ", according to the examples provided in the specification.

In response to this argument, it is argued that the expression is not explicitly defined in the specification. The meaning of "self sealing" is ambiguous as evident by Figure 1 and its description on page 5, lines 5-17. Figure 1 sets forth two types of "self sealing": is it self-sealing valve (8) or self-sealing port (14)? Additionally, neither the claims nor the specification define or require the self-sealing opening valve to have a particular structure.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 5, 6, 8-10, 14, 15, 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined teachings of EP 0 666 081 ('081), US 3,788,521 ('521) and US 3,976,223 ('223).

EP '081 teaches gel wound dressing comprising material comprising:

a) from about 0.05% to 10% by weight of natural gelling agent;

b) from about 1.0% to 10% by weight of hydrocolloid;

c) from about 5.0% to 30.0% by weight of an alkylene glycol and

d) at least 50% by weight of water.

Therefore, EP '081 teaches the gel wound dressing composition as claimed by claim 5. The gel composition of the reference can be extruded in the form of gel through

a nozzle (page 2, lines 20-24; page 3, lines 14-18). The gel of the reference has viscosity of 50-800 Pas, as required by claim 18, (page 2, lines 54-55). The reference disclosed the gel conforms readily to the shape of the wound particularly when the wound includes a cavity, and that teaching suggests treating wound of sinus cavities (page 2, lines 8-9). The wound dressing is packaged and sterilized, as required by claims 6, 10 and 15.

Although EP '081 teaches delivery of gel wound dressing from a nozzle, it does not teach delivery of the gel wound dressing from aerosol barrier.

US '521 teaches pressurized aerosol package comprises rigid container having dispensing valve, and collapsible container inside the rigid container and pressurized gas filled in between the two containers (abstract; col.3, lines 33-40, figures). The pressurized container is self-sealing according to applicants' definition to self-sealing as "because there is positive pressure in the container, the vessel can be made self sealing". The aerosol package is made large enough to provide multiplicity of one-shot applications (col.10, lines 43-44), i.e. multi-doses. Applicants disclosed at page 3, lines 34-36 that the aerosol vessel disclosed by US '521 is one of the preferred aerosol vessel used to deliver the gel of the present invention. US '521 teaches that the discharged product from the aerosol has a uniform density and maintained a predetermined physical characteristic all the life of the package (col.7, lines 47-52; col.10, lines 35-38). US '521 disclosed method for assembling the package including the steps of filling the outer container with a gas, filling the inner container with the

product, followed by inserting a valve on the neck of the containers with a press fit (col.12, lines 41-53).

However, US '521 does not teach delivering gel from the disclosed aerosol package.

US '223 teaches an aerosol container containing gel comprising carboxymethyl cellulose, gelling agent and alginate. The gel comprises polyethylene glycol, which reads on gelling agent and alkylene glycols claims by claim 5 (col.6, lines 28-31, 34, 48, 63-65; col.7, lines 29-30; col.9, lines 20-23, 45-48, 51-55). The aerosol containing gel used to treat burns, which reeds on wound (col.9, lines 20-55). Therefore, the art recognized at the time of the invention that wound dressing gel can be delivered from an aerosol package. The aerosol is provided by mechanical stream break up features, i.e. self-sealing (col.2, lines 65-67). The aerosol disclosed by the reference is not a single dose container as implied by the effort made to avoid contamination of the contents during use.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide wound dressing gel deliverable from a nozzle for treating cavities comprising natural gelling agent, hydrocolloid, alkylene glycol and water as disclosed by EP '081, and one having ordinary skill in the art knowing that wound dressing gels can be delivered from an aerosol package as disclosed by US '223 would have been motivated to replace the delivery means that have a nozzle with an aerosol package, and further use the aerosol package disclosed by US '521 having inner and outer container separated by pressurized gas, motivated by the teaching of US '521 that

the discharged product from such as aerosol has a uniform density and maintained a predetermined physical characteristic all the life of the package, with reasonable expectation of having wound dressing gel delivered from an aerosol package having inner container and outer container separated by a pressurized gas and meanwhile the delivered gel will have a uniform density and maintain a predetermined physical characteristic all the life of the package.

The combined teaching of the references implies method of delivery of the wound dressing gel into the wound as required by claim 15.

Regarding claims 6, 9, 10, 15, 19 and 20 that require sterilization of the gel, it is obvious to one having ordinary skill in the art at the time of the invention to sterilize any wound dressing before application to the wound to avoid contamination of the tissue already compromised by the existing disorder, with reasonable expectation to accomplish the step of sterilization of the gel composition prior or after loading into the aerosol container to obtain barrier aerosol containing sterile gel that can be applied safely to the tissue without pain with avoidance of contamination of tissue already compromised by the wound or burn.

Regarding claim 14 that teaches treating sinuses, one having ordinary skill in the art will be motivated to use the gel composition delivered by aerosol of the combined teachings of the references to treat sinuses because EP '081 suggested delivering the wound dressing gel to the body cavities, and that encompasses sinuses cavities, and one having ordinary skill in the art would have been motivated to use the aerosol because US '223 teaches aerosol gel is protected from contamination, and US '521

teaches that products delivered from pressurized aerosol will have a uniform density and maintain a predetermined physical characteristic all the life of the package.

Response to Arguments

7. Applicant's arguments filed 07/03/2007 have been fully considered but they are not persuasive. Applicants argue that:

- Although '081 does disclose a gel, '081 does not disclose a method of, and a vessel, for safely and efficiently dispensing multiple doses of wound-treating gel where the gel is in gel form in the container, and the vessel's self- sealing characteristic minimizes the contamination of the gel after the use of the vessel.

- Applicants argue that the purpose of the package of '223 is to separately store a plurality of flowable substances in a single package from which such substances may be dispensed. US '223 teaches only the lower chamber of the outer container is pressurized with a gas through a self-sealing plug in the container bottom. Since only the lower chamber of the outer container of '223 is pressurized with a gas through a self-sealing plug, the container in '223 is not self-sealing as required in the rejected claims. US '223 does not address the avoidance of contamination during use, only with respect to storage.

- Applicants argue that the addition of '521 does not make up for the deficiencies of the other two documents. It is cited in the specification as showing one example of the general "type" of vessel used. However, as noted in the action, '521 does not teach delivering gel.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections

are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In this case, the rejection is based on the combined teachings of EP '081, US '521 sand US '223. As applicants themselves admit, the claimed gel composition is disclosed by EP '081. The only difference between the reference and the present claims is the packaging of the present gel composition and its delivery from an aerosol. EP '081 suggests coating a fibrous material with a gel extruded from a nozzle. EP '81 disclosed the gel composition is sterilized and autoclaved without destruction.

US '223 is relied upon for teaching gel can be delivered from a pressurized aerosol container. US '223 is interested in making gel in aerosol for spraying. US '223 solved problem of keeping reactive components that may interfere with one another prior to application apart until dispersion from the container. It necessary follows from the teaching of EP '081 and US '223 that one would use single compartment vessel when there was no issue of reactivity or degradation of components of the composition.

Therefore, US '521 was involved in the rejection for teaching aerosol container having single inner and single outer container separated by pressurized gas, because US '521 teaches that the discharged product from such as aerosol has a uniform density and maintained a predetermined physical characteristic all the life of the package.

Additionally, the dispensing valve disclosed by US '223 is kept shut with a compression spring [30] that prevents the flowable materials present in the containers from entering into the exit passageway, col.3, lines 28-47. The exit ports are opened by

depressing the compression spring to actuate the dispensing valve, col. 4, lines 35-40. Once actuated, the "the gas under pressure in pressure tight chamber B" forces the piston upward, pushing the flowable materials through the exit passageway and out through the dispensing valve, col.4, lines 38-45. As a result, "a uniform, metered amount of the flowable material" is discharged from the package, col.4, lines 46-58. US '223 indicates that "dispensing valve assembly" forms "a pressure tight closure when the valve is closed, col.3, lines 20-24. This structure described by US '223 can be characterized as "self-sealing" since the compression spring [30] in combination with the lower pressurized container keep the valve shut. US '223 states that the "relative metering" of the flowable material from the container "is constant throughout the life of the dispenser," indicating that it contains "multiple doses," as required by claim 1, col.4, line 66-col.5, line 2.Further, self sealing valve disclosed by US '223 reads on the present self-sealing in light of applicants' disclosure and figure 1 that set forth two meaning for self-sealing, and one of them is the valve in the bottom of the container used to fill the container with the pressurized gas.

In considering the disclosure of the reference, it is proper to take into account not only the specific teachings of the reference but also the inferences which one skilled in the art would reasonably be expected to draw therefrom. *In re Preda*, 401 F.2d 825, 826, 159 USPQ 342, 344 (CCPA 1968). The rational to modify or to combine the prior art does not have to be expressly stated in the prior art; the rational may be expressly or impliedly contained in the prior art or it may be reasoned from knowledge generally available to one of ordinary skill in the art. The reason or motivation to modify the

reference may often suggest what the inventor has done, but for a different purpose or to solve different problem. It is not necessary that the prior art suggest the combination or modification to achieve the same advantage or result discovered by applicant. *In re Linter*, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972). A conclusion of obviousness under 35 U.S.C. 103 (a) does not require absolute predictability, only a reasonable expectation of success; and references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. *In re Bozek*, 163 USPQ 545 (CCPA 1969).

In the light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the claims would have been *prima facie* obvious within the meaning of 35 U.S.C. 103 (a).

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 5,976,573 teaches pharmaceutical composition in the form of gel that can be sprayed into the nasal cavity including nasal sinuses, such a gel composition has relatively high viscosity between 400 to 1000 cp such that resists being cleared from the mucosal surfaces and remains on the mucosal surfaces for relatively long periods of time (abstract; col.4, lines 38-41, 60-62; col.11, lines 15-20; claim 21 and 34). The gel is sprayed using aerosol container comprises multiple doses (col.8, lines 33-38; col.9, lines 26-31). The gel composition comprises a 5-15% suspending agent including carboxymethyl cellulose that read on hydrocolloid, dispersing agent

including Pluronic that reads on gelling agent and alkylene glycols, and water (col.5, lines 30-35, 67; col.6, line 1).

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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